UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE TESTIMONY OF DRS. DAVID SCHWARTZ, DAVID KATZ, LEE-JEN WEI, MINDY KURZER, RICHARD GOODMAN, AND DAVID GORTLER

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., Quincy Bioscience Manufacturing, LLC, and Mark Underwood (collectively, "Quincy") respectfully submit this memorandum of law in opposition to Plaintiffs the Federal Trade Commission ("FTC") and the New York Attorney General's Office's ("NYAG", and collectively with the FTC, "Plaintiffs") motion to exclude the testimony of Drs. David Schwartz, David Katz, Lee-Jen Wei, Mindy Kurzer, Richard Goodman, and David Gortler filed on September 1, 2022 ("Motion"). (Dkt. Nos. 302-305.)

PRELIMINARY STATEMENT

Plaintiffs' kitchen-sink motion to exclude the testimony (or portions thereof) of six of Quincy's expert witnesses should be denied in its entirety. As discussed in Quincy's summary judgment briefing, Plaintiffs and their experts continue to ignore the relevant substantiation standard that applies to marketing dietary supplements—the flexible "competent and reliable scientific evidence" standard that the FTC itself enunciated in *Dietary Supplements: An Advertising Guide for Industry* (the "FTC Guidance") over two decades ago, which necessitates an award of summary judgment in Quincy's favor. Instead, Plaintiffs seek to exclude Defendants' experts by misstating and mischaracterizing these experts' testimony, applying a double standard in trying to hold Quincy's experts to a higher standard than their own, and resorting to sweeping generalizations of law without articulating why those principles warrant exclusion in this case.

First, Plaintiffs' assertion that Quincy's experts (Drs. David Schwartz, David Katz, and Lee-Jen Wei) are offering "legal opinions" is just plain wrong. Quincy's experts (unlike Plaintiffs' experts) reviewed and relied on the "competent and reliable scientific evidence" standard for dietary supplement manufacturers set forth in the FTC Guidance. Quincy's experts evaluated Quincy's scientific evidence under the FTC's own framework (which admittedly applies to the NYAG's claims as well) and through the lenses of their respective professional expertise and

judgment, and opined that Quincy's evidence easily satisfies (and indeed surpasses) that standard. Understanding the applicable standards is obviously essential to forming expert opinions that are relevant to the claims and defenses and that "fit" the case. It does not, in any way, transform Defendants' experts' scientific opinions into legal opinions. Plaintiffs' experts (by contrast) utterly ignore the relevant standard and are trying to hold Quincy to a standard that the FDA applies to new drug applications—not dietary supplements. That disconnect is extraordinary.

Second, Plaintiffs' claim that any references to the FDA should be excluded as irrelevant is incredible, in light of the fact that the FTC Guidance itself was issued *in response* to the Dietary Supplement Health Education Act of 1994 ("DSHEA"), an FDA statutory and regulatory framework governing dietary supplements, and expressly incorporates FDA law, not to mention Plaintiffs' own reliance in this case on allegations in a now-closed FDA warning letter.

Third, Dr. Katz—a medical doctor, clinician and former director of Yale University's Yale-Griffin Preventative Research Center—who has a graduate degree in public health—is more than qualified to evaluate a seemingly unrelated regression analysis that provides additional support for his opinion that Prevagen® provides a clinically meaningful and statistically significant benefit. Plaintiffs' argument otherwise strains credulity because Plaintiffs' own experts on the topic have no experience conducting the same statistical analysis.

Fourth, Plaintiffs' attempt to exclude the rebuttal testimony of Dr. Wei—a professor of biostatistics at Harvard with whom Plaintiffs' own experts agree—has no merit. Dr. Wei reviewed the statistical analysis of the Madison Memory Study, opined that it constitutes competent and reliable statistical evidence of Prevagen's benefit, and further opined that Plaintiffs' experts applied outdated statistical concepts that no longer represent the prevailing view in his field.

Fifth, Plaintiffs' attempt to exclude portions of Dr. Mindy Kurzer's testimony because she is not an expert in memory is nothing more than a strawman argument, as Dr. Kurzer is not being offered as an expert in memory. Rather, she opined on whether Quincy's proffered substantiation is supported by competent and reliable scientific evidence, and it is black-letter law that qualified scientists can make such a determination even if their specific area of focus does not precisely match the underlying discipline. Dr. Kurzer's extensive experience in designing, conducting, analyzing, and evaluating clinical trials involving dietary supplements and dietary ingredients more than qualifiers her to opine on Quincy's proffered substantiation. Plaintiffs' mischaracterization of Dr. Kurzer's analysis of the Madison Memory Study is equally meritless. Dr. Kurzer's method of looking for traditional findings of statistical significance as well as directional trends in the data is reliable, re-creatable, and well-accepted in the relevant scientific community.

Sixth, Plaintiffs would have this Court exclude Dr. Richard Goodman's testimony simply because it cuts against one of their main theories of this case: that apoaequorin would be "completely digested" in the human stomach and therefore cannot exert a therapeutic effect. But Plaintiffs' argument is based on their own incorrect interpretation of Dr. Goodman's work, and Dr. Goodman should certainly be permitted to refute Plaintiffs' misguided (and unsupported) theory.

Seventh, Quincy's rebuttal pharmacological expert, Dr. David Gortler, properly rebuts one of Plaintiffs' own expert's broad and unsupported conclusions that Prevagen cannot work because its mechanism of action is not fully elucidated in two ways: first, by showing that a known mechanism of action is not required for drugs, let alone dietary supplements; and second, by

identifying numerous plausible mechanisms of action that Plaintiffs' expert failed to consider. This is proper rebuttal.

Finally, Plaintiffs' attempt to exclude Drs. Kurzer, Schwartz, and Katz's testimony concerning plausible mechanisms of action should be rejected because Plaintiffs have put the issue in play by advancing an outdated and, frankly, wrong, position that apoaequorin must cross the human blood-brain barrier to have a beneficial effect on cognition. That is not true, and Quincy properly submitted opinions discussing other plausible mechanisms of action in response.

Plaintiffs' scattershot challenges to Quincy's experts' testimony aside, Plaintiffs pointedly do not challenge Quincy's expert testimony about the core issue in this case: the design, conduct, and analysis of the Madison Memory Study, (*see, e.g.,* Dkt. 225-15, Katz Report ¶¶ 16-34, 50-66; Dkt. 225-23, Schwartz Report ¶¶ 19-35, 66-68, 76-77; Dkt. 225-18, Schwartz Rebuttal Report ¶¶ 6-7, 37-48; Dkt. 225-24, Dkt. 225-18, Kurzer Report ¶¶ 31-36, 47-52; Dkt. 225-18, Wei Rebuttal Report ¶¶ 10-55; Dkt. 225-13, Alexander Report ¶¶ 8-16), or of Quincy's *in vitro*, animal, and human open-label studies relating to Prevagen or apoaequorin. (*See, e.g.,* Dkt. 225-15, Katz Report ¶¶ 15; Dkt. 225-23, Schwartz Report ¶¶ 36-58, 76-77; Dkt. 225-18, Dkt. 225-18, Kurzer Report ¶¶ 30, 80.) Thus, even if the Court were to accept all of Plaintiffs' arguments (which it should not), Defendants' experts would each still be permitted to testify at trial regarding the core issues in the case.

ARGUMENT

I. DRS. SCHWARTZ, KATZ, AND WEI ARE NOT OFFERING LEGAL OPINIONS

A. Drs. Schwartz. Katz, and Wei Properly Opine on Whether Quincy's Substantiation Constitutes "Competent and Reliable Scientific Evidence"

Plaintiffs argue that Drs. Schwartz, Katz, and Wei offered legal opinions that seek to change New York and FTC law. (Mot. at 6.) They did not, and Plaintiffs' distortion of Quincy's

experts' testimony is a common theme throughout Plaintiffs' Motion. Drs. Schwartz, Katz, and Wei are not offering legal conclusions or otherwise instructing the jury on how to decide this case. Instead, they reviewed Quincy's scientific substantiation against a set standard—the FTC Guidance—and opined that Quincy's substantiation surpassed that standard. Specifically, they opined that Quincy's substantiation amounted to "competent and reliable scientific evidence" as defined in the FTC Guidance. Whether scientific evidence is "competent and reliable scientific evidence" is undoubtedly a proper subject of expert testimony. Plaintiffs' own cases confirm as much. *See FTC v. Alcoholism Cure Corp.*, No. 3:10-CV-266-J-34JBT, 2011 WL 13137951, at *38 (M.D. Fla. Sept. 16, 2011) ("[W]hat constitutes competent and reliable scientific evidence in this case is a question of fact for expert interpretation" (quoting *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1190 (N.D. Ga. 2008))), *aff'd sub nom. FTC. v. Krotzer*, No. 12-14039-AA, 2013 WL 7860383 (11th Cir. May 3, 2013). Drs. Schwartz, Katz, and Wei are thus offering appropriate expert testimony that is consistent with the legal framework applicable to Plaintiffs' claims.

Plaintiffs make the untenable argument that, in reaching their opinions, Drs. Schwartz, Katz, and Wei should not have referenced or otherwise considered the definition of "competent and reliable scientific evidence" as set forth in the FTC Guidance. Plaintiffs would apparently prefer that Quincy's experts testify as to whether scientific evidence is "competent and reliable" in their own subjective opinions rather than evaluating the evidence within the appropriate legal and regulatory framework.[1]

[1] As set forth in Quincy's summary judgment and *Daubert* motions, Plaintiffs' and their experts' failure to apply the correct substantiation standard is fatal to their claims and warrants exclusion of Plaintiffs experts' opinions. (Dkt. Nos. 227, 307.)

Plaintiffs badly miss the mark. Expert opinions must fit both the facts and the applicable substantive law. *See Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 679 (S.D.N.Y. 2007). To this end, experts certainly need to be able to reference the law that informs their opinions. *See Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1017 (9th Cir. 2004); *United States v. Liew*, No. CR 11-00573-1 JSW, 2013 WL 6441259, at *8 (N.D. Cal. Dec. 9, 2013) ("The Government does not dispute that experts may refer to their understanding of the law without usurping the Court's role." (citing *Hangarter*)). In *Voter Verified, Inc. v. Premier Election Sols., Inc.*, No. 6:09-CV-1968-ORL-19, 2011 WL 87306, at *4 (M.D. Fla. Jan. 11, 2011), for example, the Court rejected a challenge to an expert's statement of the legal standard that informed his opinion. As the court saw it, the expert was "entitled to set forth the legal definitions" that he applied in reaching his conclusions, and such information underscored the court's determination that the expert's testimony was "reliable and admissible." *Id.*; *see also The Medicines Co. v. Mylan Inc.*, No. 11-CV-1285, 2014 WL 1758135, at *6 (N.D. Ill. May 2, 2014) ("Dr. Linck may testify regarding the legal standards upon which she relies for her opinions."); *Sancom, Inc. v. Qwest Commc'ns Corp.*, 683 F. Supp. 2d 1043, 1055-56 (D.S.D. 2010) (expert opinion that incorporated definition set out in tariff was not inadmissible legal opinion); *Arlaine & Gina Rockey, Inc. v. Cordis Corp.*, No. 02-22555-CIV, 2004 WL 5504978, at *24 (S.D. Fla. Jan. 5, 2004) ("Murray may explain his own understandings of the law and apply it to opinions of the scientific experts on the issues of fact, without giving expert opinions as to what the law is.").

Drs. Schwartz, Katz, and Wei thus appropriately—indeed, *necessarily*—offered their opinions that Quincy's substantiation evidence was "competent and reliable" against the backdrop of the FTC Act and FTC Guidance.

Dr. Wei. Plaintiffs' discussion of Dr. Wei's "legal opinions" is thin. They assert that Dr. Wei explained that he "reviewed the FTC's Guidance" and stated that "'randomized, clinical trials are not required' for dietary supplements." (Mot. at 9 (quoting Dkt. 225-26, Wei Rebuttal Report ¶¶ 13-14).) But Plaintiffs fail to articulate how reviewing and summarizing the FTC Guidance amounts to an impermissible legal conclusion or an attempt to instruct the jury. Dr. Wei considered the Madison Memory Study against the standard set forth in the FTC Guidance (as well as from the perspective of professionals in biostatistics) and concluded that it constitutes "competent and reliable evidence that apoaequorin provides the stated benefit to the relevant group of individuals that was the stated focus of the study." (Dkt. 225-26, Wei Rebuttal Report ¶ 55.) That is not a legal opinion. Rather, it is a scientific opinion arrived at against the backdrop of regulatory guidance.

Dr. Katz. Plaintiffs similarly point to Dr. Katz's statement in his rebuttal report that he reviewed the FTC Guidance to see what "the FTC has told the dietary supplement industry in terms of what constitutes a reasonable basis for claims relating to supplements." (Mot. at 9 (quoting Dkt. 225-16, Katz Rebuttal Report ¶ 2).) Plaintiffs take issue with Dr. Katz's "conclusion" that "the FTC Guidance 'does not require human clinical trials.'" (*Id.* (quoting Dkt. 225-16, Katz Rebuttal Report ¶ 20).) But Plaintiffs misleadingly truncate Dr. Katz's discussion of the FTC Guidance. What Dr. Katz *actually* said is that "[t]he FTC Guidance states that dietary supplements are subject to a flexible substantiation standard that considers *all* forms of competent evidence and reliable scientific evidence (including information literature review and animal studies), and does not *require* human clinical trials." (Dkt. 225-16, Katz Rebuttal Report ¶ 20) (emphasis added.) And, in reaching his ultimate opinion, Dr. Katz looked at the totality of Quincy's substantiation (including animal studies, *in vitro* studies, open-label trials, and the Madison Memory Study) and

explained that Quincy followed a well-established "stepwise" pattern of substantiation: *first*, science generated interest in the role of apoaequorin as a neuroprotective agent; *second*, preclinical research, including animal and laboratory studies, advanced the hypothesis that apoaequorin is safe and effective; and *third*, "a randomized, double-blind, placebo controlled trial in human volunteers (the MMS) provided evidence that apoaequorin benefits the intended target population." (*Id.* ¶¶ 27-28.) Dr. Katz, an internal medicine doctor who treated patients suffering from cognitive decline and who has "fairly extensive training in biostatistics," opined that the Challenged Claims were substantiated by "competent and reliable scientific evidence." (Ex. C, Katz Tr. 28:19-29:1; Dkt. 225-16, Katz Rebuttal Report ¶¶ 20, 37.)

Plaintiffs do not explain in their Motion how that well-supported opinion constitutes a naked conclusion aimed at directing the jury on how to fill out the verdict sheet—because it does not. Plaintiffs instead claim that Dr. Katz "completely overlooks the obvious flaws in Defendants' research" and criticize his statement that the Madison Memory Study's suggestive benefits meet the standard for competent and reliable evidence. (Mot. at 9 (quoting Dkt. 225-16, Katz Rebuttal Report ¶ 24).) But those are nothing more than critiques of Dr. Katz's substantive opinion that Quincy's substantiation constitutes "competent and reliable scientific evidence." Plaintiffs can take those complaints up on cross-examination. They do not warrant exclusion of Dr. Katz's opinions.

Dr. Schwartz. Plaintiffs' criticisms of Dr. Schwartz's references to the FTC Guidance similarly fall flat. The FTC Guidance informed Dr. Schwartz's opinion that—after viewing "the totality of the available evidence"—the Challenged Claims were supported by competent and reliable scientific evidence. (Dkt. 225-23, Schwartz Report ¶ 76.) Dr. Schwartz (unlike Dr. Katz and Dr. Wei) offered additional opinions that Prevagen's packaging complied with the FDA's

regulations, that the Challenged Claims do not meet the definition of disease claims as defined by the FDA, and that Quincy's substantiation efforts far exceeded the industry standard. (*Id.* ¶¶ 9, 10.) Those opinions are not "legal opinions." (Mot. at 8.) They are the proper subject of expert testimony, they are backed up with evidence, and they fall squarely within Dr. Schwartz's expertise as a regulatory consultant to the health care industry, including dietary supplement companies. (Ex.[2] A, Schwartz Tr. 13:15-25.) Indeed, courts routinely admit expert testimony regarding regulatory compliance. *See In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 474 (S.D.N.Y. 2016) ("[C]ourts have consistently found that expert testimony regarding FDA regulations and a company's compliance under that regulatory scheme is admissible."). And Dr. Schwartz—who regularly assists the dietary-supplement industry in compliance efforts—can appropriately offer an opinion about the industry practice viewed against the regulatory framework that governs the industry. *See, e.g.*, *M. G. v. Bodum USA, Inc.*, No. 19-CV-01069-JCS, 2021 WL 718839, at *17 (N.D. Cal. Feb. 24, 2021) ("As a general rule, experts may refer to their understanding of the requirements of statutes and regulations in offering testimony about industry norms and practices.").

Plaintiffs also argue that Quincy's experts' conclusions are not based on an evaluation of what evidence experts in their respective fields (neuroscience, internal medicine, and biostatistics) would consider to be competent and reliable evidence. (Mot. at 7, 10.) But Drs. Schwartz, Katz and Wei are unquestionably experts in their fields, and they did not abandon their professional experience, judgment and identities when they reviewed Quincy's substantiation. They considered the totality of the facts surrounding Quincy's substantiation in a manner that is consistent with the FTC Guidance and that aligns with their own professional judgment. More to the point, however,

[2] All references to "Ex. __" are to the Declaration of Glenn T. Graham dated October 3, 2022 and filed herewith.

Plaintiffs' complaints amount to nothing more than substantive criticism of the conclusions that Drs. Schwartz, Katz, and Wei reached. Those substantive criticisms do not transform their scientific expert opinions into legal conclusions, and they certainly do not warrant exclusion.

The cases that Plaintiffs cite—which Plaintiffs tellingly do not discuss (another common theme throughout Plaintiffs' Motion)—show the types of impermissible legal conclusions that courts *do* exclude. In *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d 430, 498 (S.D.N.Y. 2018) (Mot. at 8), for example, the court excluded an expert's opinion that certain trader-level data was required to be produced in discovery and that its importance "outweigh[ed] the burden on defendants of making this production." And in *Hygh v. Jacobs*, 961 F.2d 359, 364 (2d Cir. 1992) (Mot. at 10), the Second Circuit held that the trial court should have excluded an expert who offered an opinion in a use-of-force case that the officer's conduct was not "'justified under the circumstances,' not 'warranted under the circumstances,' and 'totally improper.'" To the Second Circuit, the proffered expert opinions amounted to nothing more than telling the jury how to decide the case. *Id.* The facts of those cases are a far cry from Defendants' experts' analysis of the evidence against a legal framework.

In short, Drs. Schwartz, Katz, and Wei are not offering impermissible legal opinions. They properly analyzed Quincy's substantiation both through the lenses of their respective professions and against the applicable standard set out in the FTC Guidance and then offered scientific expert opinions about Quincy's substantiation of the Challenged Claims (and, in the case of Dr. Schwartz, its regulatory compliance). These are not impermissible legal opinions and they should be admitted at trial.

B. References to the FDA are Relevant

Plaintiffs next argue that any references to the FDA made by Drs. Schwartz, Katz, and Wei are irrelevant. (Mot. at 10-12.) On this point, it is unclear exactly what opinions or testimony

Plaintiffs are asking this Court to exclude. Plaintiffs refer generally to opinions about "the FDA, DSHEA, other FDA statutes, regulations, or drug approvals, and the actions of other dietary supplement manufacturers." (*Id*. at 12.) Plaintiffs fail to point to any specific opinions that Drs. Schwartz, Katz, or Wei offered on this point and fail to explain how those opinions are irrelevant. On these gaps alone, this portion of Plaintiffs' Motion should be denied.

In any event, references to the FDA are certainly relevant to this case. Indeed, the FTC Guidance—the core of this case—was enacted in response to DSHEA and expressly incorporates FDA law. As the Court explained in *United States v. Bayer Corp*., No. CV 07-01(JLL), 2015 WL 5822595, at *3 (D.N.J. Sept. 24, 2015), Congress recognized the benefits of dietary supplements and "enacted DSHEA to ensure that [dietary] supplements [could] be marketed and sold without following the stringent requirements imposed on drugs." That meant that although drugs had to be pre-approved by the FDA and "supported by randomized, placebo-controlled, double-blind clinical trials, dietary supplements need not." *Id.* (internal citation omitted); *see also* S. Rep. 103-410, at 24 (1994) ("[T]he scientific evidence supporting a claim [for dietary supplements] should not be held to the same standard used in evaluating new drug applications."). In light of this background, Dr. Schwartz's opinion that the Challenged Claims are not disease claims—and, as a result, not subject to the drug standard—is both relevant and material. Indeed, Plaintiffs themselves have injected that issue into this case by straying from the FTC's own definition of "competent and reliable scientific evidence" as it pertains to dietary supplements and seeking to hold Quincy's substantiation evidence to a standard that (in the words of Plaintiffs' own experts) would amount to the drug standard. What's more, in this action, Plaintiffs themselves rely on allegations from a 2012 warning letter that the FDA issued relating to Quincy—an inquiry that

was closed without enforcement activity by the FDA. Plaintiffs' blanket request to bar all references to the FDA should therefore be rejected.

Defendants' experts' references to the recent FDA approval of Aduhelm is also a relevant benchmark against which to analyze the substantiation for Prevagen. Aduhelm was granted accelerated *drug* approval by the FDA, despite substantial disagreement within the scientific community concerning the strength of the evidence and the safety of the drug, among other things, not to mention the small dataset considered by the FDA. Thus, while the regulatory approval of Aduhelm may not be *directly* relevant to the substantiation of the Challenged Claims, it is relevant to the extent it reflects the nuanced and flexible approach the government takes with respect to product substantiation, even when the product is a drug like Aduhelm with severe side effects and heavily disputed evidence of efficacy. It defies logic that the FTC could apply a more rigid standard to a dietary supplement product like Prevagen that is demonstrably safe, has been shown to work, and that, under federal law, does not require the same level of substantiation as that required for new drug applications. Far from confusing the jury, Defendants' experts' testimony about FDA standards generally, as well as the recent approval of Aduhelm, will provide relevant context for understanding where and how dietary supplements fit into the applicable regulatory framework.

C. The References to the FTC Guidance in Reports of Drs. Schwartz, Katz, and Wei are Accurate and Will Not Confuse the Jury

Plaintiffs argue that the views expressed by Drs. Schwartz, Katz, and Wei about the FTC Guidance are "wrong." In Plaintiffs' view, Drs. Schwartz, Katz, and Wei "cherry picked" portions of the Guidance, highlighting some provisions but not others. (Mot. at 13.) That argument is particularly disingenuous; Plaintiffs appear to be arguing that Quincy's experts did not consider *enough* of the FTC Guidance when, at the same time, their experts admittedly *ignored* the FTC

Guidance in its entirety. In any event, Drs. Schwartz, Katz, and Wei do not, as Plaintiffs suggest, skip over the statement in the FTC Guidance that "[t]here are . . . some principles generally accepted in the scientific community to enhance the validity of test results," including the uncontroversial statement that a "a study that is carefully controlled, with blinding of subjects and researchers, is likely to yield more reliable results." (Dkt. 225-6, FTC Guidance at 9.) Drs. Schwartz, Dr. Katz, and Dr. Wei are each exceedingly well-credentialed scientists (Plaintiffs do not argue otherwise) who are, of course, familiar with those general principles and factored them into their review of Quincy's proffered substantiation.

As detailed above, the FTC Guidance informed Dr. Schwartz's, Dr. Katz's, and Dr. Wei's overall opinions that the proffered substantiation was "competent and reliable scientific evidence" under the FTC Guidance. And for good reason—the FTC Guidance is the relevant standard. And their disagreement with Plaintiffs' experts' application of a rigid (and inapplicable) drug-level standard was not on whether or not a randomized, controlled trials lead to more reliable results than trials that are not similarly controlled. It was based on the fact that the FTC Guidance explicitly does not limit the evidence that can be considered to *only* drug-level randomized, controlled trials. (*Id.* at 12 ("There is no set protocol for how to conduct research that will be acceptable under the FTC substantiation doctrine.").) They accordingly did not "cherry pick" anything out of the FTC Guidance. They followed its totality-of-the-evidence approach to a tee; Plaintiffs' experts completely ignored it.[3]

Finally, Plaintiffs argue that Drs. Schwartz, Katz, and Wei overlooked the statement in the FTC Guidance that an advertiser that asserts a certain level of support for its claims must, in fact,

[3] Plaintiffs' authority does not hold otherwise. As addressed in detail in Defendants' motion for summary judgment, the cases cited on page 12 of Plaintiffs' Motion in which courts required an RCT did so for specific reasons not present here, namely that they involved disease claims as opposed to the structure-function claims being challenged here, or the defendant offered little to no substantiation for the challenged claims. (Dkt. 278 at 14-16.)

have that level of support. (Mot. at 14.) According to Plaintiffs, because Quincy claimed to have an RCT, it was required to have that level of support. This argument falls flat. For one thing, *Quincy conducted an RCT*—the Madison Memory Study—that supports the Challenged Claims. The Court already recognized as much. *See FTC v. Quincy Bioscience Holding Co., Inc.*, 272 F. Supp.3d 547, 553 (S.D.N.Y. 2017). And although Plaintiffs do not articulate it this way, they are presumably arguing that the alleged "clinically shown" claims—a subset of the Challenged Claims—must be substantiated by an RCT. But Plaintiffs intentionally kept that issue out of this case by deciding not to put forward any consumer-perception evidence as to how reasonable consumers interpret the phrase "clinically shown."[4] In any event, Drs. Schwartz, Katz, and Wei offered opinions that Quincy's substantiation evidence, including the Madison Memory Study, was "competent and reliable scientific evidence" for all of the Challenged Claims.

II. DR. KATZ'S OPINIONS REGARDING THE SEEMINGLY UNRELATED REGRESSION ANALYSIS ARE BOTH RELIABLE AND ADMISSIBLE

Plaintiffs' criticisms of Dr. Katz's expertise are meritless and therefore his opinions related to a seemingly unrelated regression ("SUR") analysis of the Madison Memory Study data conducted by Howard J. Beales, Ph.D. are admissible. Plaintiffs argue that Dr. Katz is not qualified to opine on the SUR analysis because he is not an expert in econometrics.[5] But Plaintiffs seek to impose too stringent of a requirement on Dr. Katz while simultaneously applying a far *easier* standard to their own experts who opine on the SUR analysis. "[C]ourts allow experts to testify

[4] Indeed, there are at least two different interpretations in the record of what "clinically shown" could mean. Plaintiffs are apparently taking the position that it means shown through a heightened, drug-level RCT, whereas Dr. Wei, a highly credentialed statistician, interpreted the phrase to convey a showing of clinical (as opposed to statistical) improvement. (Ex. B, Wei Tr. 46:21—48:3.)

[5] Dr. Katz is a founder and former director of Yale University's Yale-Griffin Preventative Research Center, former Director of Medical Studies in Public Health at Yale University School of Medicine, and former Yale course director for Epidemiology, Public Health, Preventative Medicine, and Biostatistics, with decades of clinical and research experience and over 200 peer-reviewed publications,

to matters within their general expertise" even if the expert "lack[s] qualifications as to specific technical matters within their field." *In re Methyl Tertiary Butyl Ether (MTBE) Prod. Liab. Litig.*, 643 F. Supp. 2d 471, 478 (S.D.N.Y. 2009).

Dr. Katz's SUR-related opinion must be understood in its context. Dr. Katz opined that from both a statistical and clinical perspective, competent and reliable scientific evidence supports the Challenged Claims. (Dkt. 225-15, Katz Report ¶¶ 7-8.) As support for this opinion, Dr. Katz relied on, among other things, various statistically significant findings from the Madison Memory Study. (Dkt. 301-1 ¶ 16.) Dr. Katz's opinions were buttressed by, but in no way depend on, Dr. Beales' SUR analysis, which Dr. Katz reviewed and analyzed in connection with his expert report submitted in this action as well as his prior work for Quincy in connection with the FTC's pre-suit investigation.

Plaintiffs' characterization of Dr. Katz's professional experience as having "some experience in biostatistics" (Mot. at 15) is very misleading. In fact, Dr. Katz's education involved "fairly extensive training in biostatistics" and he "focused especially on statistical elements useful for [him] in the clinical research center," such as analyzing clinical trial data like the Madison Memory Study. (Ex. C, Katz Tr. 28:19—29:1.) Dr. Katz was trained in the SAS programming language used in Dr. Beales' SUR analysis as well as other routine methods of biostatistics, taught biostatistics courses at Yale University, and even went on to become the course director in biostatistics for Yale medical students for roughly a decade. He has also "coauthored [] five editions of a textbook on epidemiology, biostatistics, [and] preventative medicine in public health." (Ex. C, Katz. Tr. 28:19—29:7; Dkt. 225-15, Katz Report ¶ 2.) Dr. Katz is therefore eminently qualified to opine on statistical analyses like the SUR analysis, particularly in the context of analyzing clinical trial data.

Given this background, Dr. Katz's statistical experience therefore qualifies him to render these opinions, even without specific experience with econometrics and/or the SUR method as Plaintiffs argue. *See Roberts v. Genting N.Y. LLC*, No. 14-CV-257 (ILG) (VMS), 2021 WL 950055, at *9 (E.D.N.Y. Mar. 12, 2021) (admitting an expert with "qualifications in a general field closely related to the subject matter in question"). Indeed, Plaintiffs' own experts who opine on Dr. Beales' SUR analysis, Dr. Peter Malaspina and Dr. Janet Wittes, have no experience performing a SUR analysis prior to this litigation. Thus, by Plaintiffs' own logic, if Dr. Katz is not qualified to opine on the SUR analysis, neither are Drs. Malaspina or Wittes. Dr. Malaspina, for example, admittedly relied on the SAS user guide to determine which inputs to enter into the SAS system to conduct his analyses, because he had no "specific memory" of ever using the program. (Dkt. 308-13, Malaspina Tr. 55:9-13; 71:10-17; 135:15—136:15.) Even worse, Dr. Wittes admitted that she "had no experience with a SUR analysis" prior to this case, and was "not sufficiently familiar with the SUR model to be able to opine on the applicability of the model in this case." (Dkt. 258-4, Wittes Rebuttal ¶ 19; Dkt. 258-11, Wittes Tr. 145:3—146:18.) Nevertheless, she asserted that she was "familiar with statistical methods in general and can comment on the statistical test as applied to the case of the Madison Memory Study." (Dkt. 296, Wittes Pretrial Declaration ¶ 21.) Plaintiffs appear to believe that a general knowledge of statistics is sufficient for Dr. Wittes to opine on the SUR analysis, but insufficient for Dr. Katz to do the same. This court should reject Plaintiffs' attempt to hold Quincy's experts to a higher standard than their own.

Plaintiffs' misguided attempt at characterizing Dr. Katz as a mouthpiece for Dr. Beales' opinions also fails. Indeed, the first case Plaintiffs cite, *Hart v. BHH, LLC*, *rejected* a "parroting" argument and held that a testifying expert may present the findings and conclusions of others so

long as the expert is independently qualified to interpret such results. No. 15-CV-4804, 2018 WL 3471813, at *8 (S.D.N.Y. July 19, 2018). Where, like Dr. Katz, an expert has experience in the relevant fields of biostatistics and clinical trials, he is "more than qualified to interpret the[] results" of Dr. Beales' SUR analysis. *Id.* *Malletier v. Dooney & Burke, Inc.*, 525 F. Supp. 2d at 664, is similarly unhelpful to Plaintiffs' position. In *Malletier*, the proffered expert concluded that a downturn in a particular Louis Vuitton handbag's sales was caused by the sale of particular Dooney & Burke handbag. *Id.*. The expert, a businessman with experience in brand valuation and related financial matters, based this opinion on a regression analysis that he did not conduct and was not qualified to conduct. *Id.* at 652. The expert's understanding of and experience with statistical analysis was "based on studying statistics in graduate school 30 years earlier." *Id.* The court therefore found that he was not qualified to "conduct or interpret statistical analyses," and was incapable of offering opinions about the analysis independently, instead simply relaying messages from a colleague with "judgment . . . beyond [his] ken." *Id.* at 64-66. *Dura Automotive Systems of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 615 (7th Cir. 2002), is also inapposite because the purported expert "himself lack[ed] the necessary expertise" to offer the relevant opinion. Unlike the experts in these cases, Dr. Katz is not attempting "to be the mouthpiece of a scientist in a different specialty." *Id.* at 614. Rather, he is opining on a subject well within his specialties of clinical trials and biostatistics.

Moreover, Dr. Katz's report and deposition transcript demonstrates that he did not blindly accept Dr. Beales' conclusions; rather he utilized his clinical and research background, as well as his training and experience in biostatistics to evaluate Dr. Beales' SUR analysis and reached his own conclusions. (Dkt. 225-15, Katz Report ¶¶ 35-37; Ex. C, Katz Tr. 208:9—216:16.) Specifically, Dr. Katz observed that the SUR analysis "shows a dose-response curve seen for the

full array and for many of the individual test components of that array." (Dkt. 225-15, Katz Report ¶ 36.) Dr. Katz, in turn, appropriately concluded that those findings supported the primary study hypothesis "by many measures of cognitive function, and when pooling all relevant measures of cognitive function, there is a significant benefit of Prevagen when cognitive function is objectively intact or minimally compromised." (*Id.* ¶ 37.) Because Dr. Katz "has expertise in the field covered by" the Beales report, there is no risk that he is "acting as a mere 'mouthpiece or conduit.'" *Medisim Ltd. v. BestMed LLC*, 861 F. Supp. 2d 158, 169 (S.D.N.Y. 2012), *on reconsideration in part*, No. 10 CIV. 2463 SAS, 2012 WL 1450420 (S.D.N.Y. Apr. 23, 2012).

Additionally, Plaintiffs argue that Dr. Katz "fails to realize" Dr. Malaspina's opinion that, "when Dr. Beales' SUR model is corrected . . . there is no evidence that Prevagen has a statistically significant effect on cognitive function when compared to a placebo." (Mot. at 17; Dkt. 305-2, Malaspina Report ¶ 7.) This argument fails for at least two reasons. First, Dr. Malaspina offered this opinion in a rebuttal report and therefore Dr. Katz never had an opportunity to address that specific issue. Second, and more critically, Dr. Malaspina admitted at his deposition that his purported "correction" resulted in him being *unable* to conduct the SUR as Dr. Beales designed it and that his correction is *not* "suitable for drawing reliable conclusions about the available data."[6] (Dkt. 305-2, Malaspina Report ¶ 39; ¶ 39 n.15; Dkt. 308-13, Malaspina Tr. at 88:25—91:20; 144:23—145:6.) Dr. Katz cannot be faulted for "fail[ing] to realize" an opinion of Dr. Malaspina's that was never presented to him, especially since Dr. Malaspina fully abandoned that opinion at his deposition.

[6] Because Dr. Malaspina was unable to conduct the SUR as Dr. Beales originally designed it, Dr. Malaspina was only able to achieve his purported correction by using a technique known as the "bootstrap method." (Dkt. 308-12, Malaspina Report ¶ 41.) As Dr. Malaspina conceded at his deposition, however, Dr. Beales "doesn't mention bootstrapping" in his report, nor was it a part of his original model. (Dkt. 308-13, Malaspina Tr. 128:17—129:3.)

Dr. Katz opined that the Madison Memory Study provides competent and reliable scientific evidence of Prevagen's efficacy pursuant to well-established and accepted scientific principles and methods. Dr. Beales' SUR analysis "lends strong support" to Dr. Katz's conclusion that Prevagen "appears beneficial." (Dkt. 225-15, Katz Report ¶ 36.) Dr. Katz, a clinician and researcher, is more than qualified to opine on whether the results of the SUR analysis constitute competent and reliable scientific evidence in support of the Challenged Claims, and therefore his opinions are both reliable and admissible pursuant to FRE 702 and *Daubert*. *See McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1043 (2d Cir. 1995).

III. DR. WEI'S STATISTICAL OPINIONS ARE RELIABLE AND ADMISSIBLE

Plaintiffs' Motion sets up a complete strawman argument with respect to the opinions of Dr. Wei, a tenured professor of biostatistics at Harvard University for over three decades with over 230 publications in peer-reviewed journals. (Dkt. 225-26, Wei Rebuttal Report App'x A.) Plaintiffs challenge Dr. Wei's report to the extent that "Dr. Wei purports to offer an alternative statistical method to determine whether Prevagen outperforms placebo, but he fails to apply the alternative method *he states is necessary*." (Mot. at 17-18 (emphasis added).) Plaintiffs later argue that "Dr. Wei's complete failure to make the calculations *he identified as being necessary* to his analysis demonstrates that his 'methodology' for reaching his conclusions about the Madison Memory Study is not based on good statistical grounds." (*Id*. at 20 (emphasis added).) These are blatant mischaracterizations of Dr. Wei's report.

Dr. Wei never opined, in his expert report or at his deposition, that this alternative statistical method was "necessary." Nor was it his role, as a rebuttal witness, to conduct a new statistical

analysis of the data collected from the Madison Memory Study.[7] That study was complete and its data provides substantiation for the claims challenged by Plaintiffs in this Action.

Rather than conducting a brand new analysis, Dr. Wei reviewed and responded "to the opinions presented by Drs. Sano and Wittes, who submitted expert reports on behalf of the Plaintiffs and, specifically, to respond to their criticisms of the Madison Memory Study . . ." (Dkt. 225-26, Wei Rebuttal Report ¶ 7.) Specifically, Dr. Wei opined that the framework under which Drs. Sano and Wittes analyzed the Madison Memory Study, in addition to being contrary to the standard set forth in the FTC Guidance, was both outdated and contrary to the prevailing view of experts in biostatistics as set forth by the American Statistical Association's ("ASA") "Statement on *p*-Values: Context, Process, and Purpose." (*Id.* ¶¶ 18-22, App'x C.) Plaintiffs are not challenging this opinion, likely because their own expert, Dr. Wittes, is a member of the ASA, and testified that she "agree[s] . . . with the sentiments expressed in" the ASA Statement cited by Dr. Wei. (Dkt. 258-11, Wittes Tr. 146:19—147:9.)[8]

As an alternative to Plaintiffs' experts' outdated methods, Dr. Wei opined that a better way to assess the significance of the Madison Memory Study results is to examine all nine test results together. (Dkt. 225-26,Wei Rebuttal Report ¶¶ 23-25.) He cited two of his prior publications as support for this general statistical principle, but never opined that the specific methods outlined in these publications are "necessary," as Plaintiffs argue. Nor does Dr. Wei opine that such methods are the *only* way to analyze the nine test results together. In fact, Dr. Wei testified that there were

[7] If Dr. Wei *had* conducted an additional analysis, surely Plaintiffs would have challenged that analysis as a "post hoc" analysis, as they have argued for all analyses that were conducted after the Madison Memory Study's completion.

[8] Plaintiffs are also not challenging Dr. Wei's opinions that Quincy did not engage in post-hoc subgroup analysis, that a statistical correction for multiple comparison was not required for the Madison Memory Study, and that Drs. Sano and Wittes failed to support their critiques regarding the design and conduct of the Madison Memory Study with evidence in the record. (Dkt. 225-26, Wei Rebuttal Report ¶¶ 18-22, 31-50.)

multiple ways to accomplish this result. (Ex. B, Wei Tr. 185:14—187:12.) In addition to the method set forth in his publication, he offered yet another method in his report and deposition—the one he applied in this case—in which one can review and compare the directional trends of the various outcomes (the nine Cogstate tests measured in the Madison Memory Study). Dr. Wei opined that, because a majority of the outcomes favor the treatment group in participants scoring between a 0 and 2 on the AD8 scale, there is "a very strong signal" in favor of efficacy. (*Id.* Wei Tr. 185:14—186:16.) Accordingly, Dr. Wei concluded that, based on his review of the totality of the study results across all nine Cogstate tests, it is his "professional opinion that the Madison Memory Study does meet the FTC's competent and reliable evidence standard because Prevagen does have a positive effect on memory and cognition." (Dkt. 225-26,Wei Rebuttal Report ¶¶ 26-30.)

Plaintiffs also mischaracterize Dr. Wei's testimony as "conced[ing]" that comparing the mean scores for each outcome does not give an indication of efficacy. (Mot. at 19.) Nor does Dr. Wei's "acknowledgement" that the placebo group outperformed the treatment group on a task in the AD8 0-1 subgroup undermine his opinion. (*Id.*) Dr. Wei relied on the fact that the treatment group outperformed the placebo group on a *majority* of the Cogstate tasks. (Ex. B, Wei Tr. 185:14—186:16.) He never opined (nor have Plaintiffs' experts or anyone else suggested) that complete unanimity is required.

Plaintiffs' reliance on *Amorgianos v. National Railroad Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002), does not support their position. In *Amorgianos*, the Second Circuit excluded the plaintiff's affirmative expert witness who opined that the plaintiff's overexposure to xylene caused his alleged illness. *Id.* But in that case, the expert's opinion was "fatally flawed" because it relied on erroneous factual assumptions, because that expert admitted that he failed to consider

multiple variables that were necessary to a proper exposure analysis, and because that expert was retained by the plaintiff, who had the burden of proof to establish causation through the use of a reliable method. *Id*. Those facts are simply absent here, particularly because Quincy does not bear the burden of proof and therefore Dr. Wei was not required to conduct his own statistical analysis of the Madison Memory Study as Plaintiffs suggest. Rather, he did exactly what he was retained to do: critique Plaintiffs' experts' analysis of the Madison Memory Study data and offer an alternative interpretation of the very data that Plaintiffs' experts reviewed.

Plaintiffs' only other case citation, *Cabrera v. Cordis Corp.*, 134 F.3d 1418, 1423 (9th Cir. 1998), stands for the basic proposition that unsubstantiated and undocumented information is inadmissible under *Daubert*. (Mot. at 20-21.) In *Cabrera*, the proffered expert failed to explain how he reached his conclusions or otherwise demonstrate that he followed the scientific method as it is practiced by others in his field. *See Cabrera*, 134 F.3d at 1423. Plaintiffs do not even try to make this argument with respect to Dr. Wei, and so *Cabrera* is irrelevant. Indeed, courts have distinguished *Cabrera* where the experts explained how they reached their conclusions and pointed to evidence that their method has been generally accepted in the relevant community. *See Aguilar v. Werner Enterprises, Inc.*, 2:11-cv-HRH, 2013 WL 12097447, at *5 (D. Ariz. Jan. 9, 2013). Dr. Wei explained his methodology in detail and also pointed to a number of sources, including his own peer-reviewed publications and the ASA Statement on p-values, to demonstrate that his method (as opposed to Plaintiffs' outdated methods) is the prevailing view among statisticians.

As his rebuttal report and deposition testimony make clear, Dr. Wei reviewed and responded to the critiques lodged by Drs. Sano and Wittes pursuant to well-accepted principles in the field of biostatistics and, as such, his opinions are reliable and easily satisfy the admissibility thresholds set forth in FRE 702 and *Daubert*.

IV. DR. KURZER IS QUALIFIED TO OPINE AS TO THE EXISTENCE OF COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE

Next, Plaintiffs argue that the opinions of Mindy Kurzer, Ph.D. should be excluded because Dr. Kurzer is not an expert in memory or cognition. (Mot. at 21-25.) But Defendants are not offering Dr. Kurzer as an expert on memory and cognition or on Prevagen's clinical significance, and so their argument falls flat. Dr. Kurzer is opining on whether the studies that Defendants proffered to substantiate the Challenged Claims constitute "competent and reliable scientific evidence," and Dr. Kurzer is more than qualified to offer these opinions. She has a Ph.D. in nutritional science and has over three decades of experience performing her own research on dietary supplements and dietary ingredients, teaching PhD students, and critically analyzing scientific literature. (Dkt. 225-18, Kurzer Report ¶¶ 1-5, Ex. A.) And when asked at her deposition why she was qualified to make this determination, she testified:

> The way that I know is that I'm a very, very well-trained, experienced scientist, and I'm able to evaluate data outside of my area of expertise. I often have to do this for grant applications, for writing up of publications, et cetera. I never have the luxury of just staying within a very narrow area. And so I explained before that one of the things that I have taught in my career is I've taught students how to interpret data, how to interpret papers. They aren't necessarily published in the exact area of expertise of the person who is reading them. So a person who is experienced at clinical trials, for example, has to be able to interpret and understand animal studies and in vitro studies even though that may not be where they put most of their time and energy in their own work. It is basic understanding of science. I also understand how to evaluate the quality of journals, the quality of author of journals, and the quality of – papers from the study design, et cetera. So I believe that I am very qualified to evaluate the current understanding about cognitive function despite the fact that I don't have a Ph.D. in a related science.

(Dkt. 258-9, Kurzer Tr. 92:7—93:15.)

Plaintiffs do not appear to question Dr. Kurzer's qualifications to evaluate the proffered scientific evidence; in fact, they concede that she is an expert in "nutritional science," in "conducting clinical trials," and in "analyzing scientific literature." (Mot. at 23.) And while Plaintiff assert that this is experience is "too general" to offer opinions on cognition, they fail to

explain why it is insufficient for Dr. Kurzer to evaluate Defendants' proffered substantiation, the task that she was engaged to perform.[9] Plaintiffs require that Quincy's expert navigate an arbitrarily narrow concept of scientific analysis that their own experts themselves cannot navigate. Science is not as narrow as Plaintiffs make it.

This distinction is critical, and Plaintiffs' position is inconsistent with ones they have taken in other litigations. Indeed, in other cases, the FTC has retained experts outside of their specific areas of expertise to do exactly what Dr. Kurzer has been retained to do here: evaluate whether studies proffered to substantiate marketing claims constitutes competent and reliable scientific evidence. In *United States v. Bayer Corp.*, No. 07–01 (JLL), 2015 WL 1969300, at *2 (D.N.J. Apr. 30, 2015), the FTC alleged that Bayer had made unsubstantiated marketing claims relating to a probiotic supplement called Phillips' Colon Health. The government retained Dr. Loren Laine, a gastroenterologist with experience in clinical research and clinical practice, as an expert witness. *See id.* at *5-6. The defendant sought to exclude Dr. Lane because he did not have specific expertise in probiotics. *See id.* at *5. The court rejected the defendant's *Daubert* challenge:

> While Defendant argues that the Government's expert should be excluded in this case because he is not an expert in probiotics, this is not a case simply about probiotics and as such, Dr. Laine is not required to be a probiotics expert to be useful to the Court. This case is about whether Bayer was in possession of "competent and reliable scientific evidence" to substantiate its claims about [the product]. The issue to be decided by the Court is whether Defendant possessed or relied upon "competent and reliable scientific evidence" to support its claims that

[9] Many of the sections of Dr. Kurzer's report that are addressed in Plaintiffs' Motion ("Cognitive Function and Cognitive Impairment," "Evaluation of Cognitive Function" and "Treatment Options for Cognitive Impairment" (Dkt. 225-18, Kurzer Report ¶¶ 19-29) are background sections that set the stage for her subsequent opinions regarding Quincy's substantiation. (*Id.* ¶¶ 30-36.) To the extent there are specific "opinions" that Plaintiffs call out in their Motion as being outside of Dr. Kurzer's expertise, Plaintiffs' own expert Mary Sano, who was retained to rebut Dr. Kurzer, either failed to rebut such opinions or actually *agreed* with Dr. Kurzer, further confirming the reliability of Dr. Kurzer's testimony. For example, Plaintiffs argue that Dr. Kurzer is not qualified to opine that "it has been established that executive functioning, processing speed, and attention all influence memory." (Mot. at 21; Dkt. 225-18, Kurzer Report ¶ 80.) But Dr. Sano agrees that many of the Cogstate tests measure multiple cognitive domains, and testified that she had no basis to question or disagree with the descriptions of the Cogstate tests themselves, or the cognitive domains they are intended to measure, as reported in the MMS. (Dkt. 279-3, Sano Tr. 171:24—176:14.)

> [the product] "defends against occasional constipation, diarrhea, and gas and bloating, or that [the product] prevents, cures, or treats those symptoms." Clearly, a gastroenterologist with extensive experience in testing the effectiveness of proposed treatments for gastrointestinal issues has an expertise in an area relevant and useful to the Court's determination.

Id. at *5.[10] The court similarly refused to exclude the FTC's other expert, Dr. Frederic Bushman, who had a Ph.D. in cellular and developmental biology and ruled that his training, knowledge, skill and experience was sufficient for him to opine on what constitutes competent and reliable scientific evidence despite the lack of specific expertise in probiotics. *See id.* at *6-7.

Similarly, in *FTC v. Your Baby Can LLC*, Case No. 12-cv-2114 DMS, 2014 WL 12789110, at *3 (S.D. Cal. Mar. 18, 2014), the defendant argued that the FTC's expert, a professor of teaching and learning at Vanderbilt University, was not qualified to offer opinions on infant learning and teaching babies to read. The court found that this argument "miss[ed] the mark" because the FTC was not offering the expert "as an expert on 'infant learning' and 'teaching babies to read,'" bur rather to opine "on whether Defendants' claims about its Program 'are supported by competent and reliable scientific evidence.'" *Id.* The court accordingly drew a distinction between expertise regarding the relevant subject matter and expertise regarding the quality of the proffered scientific literature.

The FTC has also been criticized in the past for adopting too narrow of a definition of the relevant "field" for purpose of evaluating and admitting expert testimony regarding the existence of competent and reliable scientific evidence. In *FTC v. Garden of Life, Inc.*, 516 Fed. App'x 852 (11th Cir. 2013), the FTC challenged marketing claims that a dietary supplement product "help[ed] support" a child's "[b]rain development," "[c]ognitive [f]unction," "[e]ye [h]ealth & [v]ision," and

[10] Ultimately, as discussed in Defendants' motion for summary judgment, the court rejected Dr. Laine's testimony as inconsistent with the FTC Guidance. (*See* Dkt. 227 at 20-22 (discussing *U.S. v. Bayer Corp.*, 2015 WL 5822595 (D.N.J. Sept. 24, 2015).)

"[p]ositive [m]ood & [b]ehavior." *Id.* at 854. The FTC submitted declarations from two experts who stated that the defendant lacked sufficient competent and reliable scientific evidence, and the defendant submitted a rebuttal expert declaration from a clinical pharmacologist explaining the support for the challenged marketing claims and critiquing the FTC's experts' findings. *See id*. at 855. The district court viewed the case as a battle of the experts, and held that the FTC failed to satisfy its burden of proof. *See id*. at 856. On appeal, the FTC argued that the defendant's expert should not have been allowed to testify because he "was not an expert in the field of children's cognitive and behavioral development and thus was unqualified to evaluate the relevant studies." *Id.* at 857. The Eleventh Circuit disagreed, finding that the FTC failed to provide any support for such a "narrow reading of what it means to be a professional in the relevant area." *Id.*

Plaintiffs' challenge to Dr. Kurzer's testimony is based on the same flawed reasoning: that only an expert in memory or cognition is qualified to evaluate whether Defendants' proffered substantiation constitutes "competent and reliable scientific evidence." But no such rule exists, and Dr. Kurzer is more than qualified to offer such opinions in this case.

None of the cases cited in Plaintiffs' Motion supports their argument. First and foremost, they fail to cite a single case in which the expert was asked to evaluate the competency or reliability of evidence proffered to substantiate marketing claims. As discussed above, the authority on this issue (*Bayer*, *Garden of Life*, and *Your Baby Can*) demonstrates that Dr. Kurzer's expertise is more than sufficient to opine on Quincy's proffered substantiation. And Plaintiffs' remaining citations either support Quincy's position or are easily distinguishable. For example, Plaintiffs cite *Stagl v. Delta Air Lines*, 117 F.3d 76, 81 (2d Cir. 1997), for the general proposition that "[a] witness whose 'expertise is too general or too deficient' can be deemed improperly qualified." (Mot. at 21.) But the Second Circuit found that the district court *erred* in excluding expert testimony from a

mechanical engineer, who the court found to have sufficient expertise about the interaction between people and machinery to testify about the safety of an airport baggage carousel despite having no experience in airport terminal design or baggage claim systems. *Stagl*, 117 F.3d at 81-82. Likewise, here, Dr. Kurzer's extensive training and experience designing, conducting, analyzing, and evaluating scientific evidence is neither "general" nor "deficient." It is precisely the experience required to evaluate Defendants' proffered substantiation.

Nor is Dr. Kurzer's expertise in "an entirely different field or discipline," as in other cases Plaintiffs cite. For example, in *Collado v. City of New York*, 11-cv-9041 (DAB), 2017 WL 4533772, at *7 (S.D.N.Y. Sept. 27, 2017), a crime victim retained as an expert witness a police officer who had trained other officers in firearms and tactics, taught self-defense, and had training in many forms of martial arts. The court correctly held that while the officer was an expert on the use of force, he was not qualified to opine on whether "it was reasonable for [the victim] to feel he was unable to breathe." *Id.* at *6-7. Such testimony required "a medical expert on the effects of desperation or panic attacks and nothing in the record suggest[ed] that [the expert] ha[d] experience with these areas." *Id.* at *7. That is not similar to the analysis here.

Likewise, in *Lloyd v. U.S.*, No. 08-cv-9016 (KNF), 2011 WL 1327043, at *4 (S.D.N.Y. Mar. 31, 2011), the court found that a medical doctor with "extensive practical experience" was qualified "to opine about the deviation in the standard of care afforded to" the plaintiff, but that he was not qualified to opine on causation of the plaintiff's paraplegia, because he had little training in neurology, never examined or treated the plaintiff, and never treated a plaintiff with his condition. *See id.* Notably, the court ruled that although an expert "need not be a specialist in the exact area of medicine implicated by the plaintiff's injury, . . . he 'must have relevant experience

and qualifications such that whatever opinion he will ultimately express would not be speculative.'" *Id.* at *5 (quotations omitted).

Unlike in *Collado* and *Lloyd*, Dr. Kurzer's decades of experience in conducting and critically evaluating scientific evidence qualifies her to opine on the quality of Quincy's proffered substantiation, even if her research has not been specifically focused on memory or cognition.

Plaintiffs' remaining case citations are inapposite because they dealt with the specific scenario of needing industry-specific expertise regarding the design of a specific type of product *See Quintanilla v. Komori American Corporation*, No. 07-cv-2375, 2009 WL 320186 (2d Cir. Feb. 10, 2009) (whether the design of a printing press was defective); *McCullock v. H.B. Fuller Co.*, 981 F.2d 656 (2d Cir. 1992) (whether warning labels affixed to a printing/binding machine were adequate); *Trumps v. Toastmaster, Inc.*, 969 F. Supp. 247 (S.D.N.Y. 1997) (whether an electric griddle had a defective design). This Court must instead apply the case law in the specific field at issue—evaluation of the competency or reliability of evidence proffered to substantiate marketing claims—and, as courts held in *Bayer*, *Garden of Life*, and *Your Baby Can Read*, Dr. Kurzer is more than qualified to review Quincy's substantiation and offer a critical opinion that it surpasses what is required by the FTC Guidance to be competent and reliable scientific evidence.

V. DR. KURZER'S ANALYSIS OF THE MADISON MEMORY STUDY DATA IS RELIABLE, RE-CREATABLE, AND HER METHOD HAS BEEN ACCEPTED IN THE RELEVANT SCIENTIFIC COMMUNITY

Plaintiffs also seek to exclude Dr. Kurzer's analysis of the Madison Memory Study but, again, completely mischaracterize her methodology as one based "just" on Dr. Kurzer's own logic and common sense. (Mot. at 25-27.) This could not be further from the truth. Dr. Kurzer's methodology is widely accepted in the field of clinical trials and statistics.

Notably, Plaintiffs do not challenge Dr. Kurzer's qualifications or expertise in the areas of statistics, clinical trials, or interpretation of clinical trial data. They are simply seeking to exclude

Dr. Kurzer's analysis of the data collected and results reported from the Madison Memory Study. Dr. Kurzer adopted a contemporary and holistic approach to analyzing the Madison Memory Study, instead of adhering to blindly to what Dr. Wei opined were "outdated concepts of statistical significance and p-values to criticize the Madison Memory Study" adopted by Plaintiffs' experts, Drs. Sano and Wittes. (Dkt. 225-26, Wei Rebuttal Report at 6.)[11] Dr. Kurzer analyzed the data from a traditional statistical perspective—*i.e.*, whether there were statistically significant results that reached what she (and Dr. Wei and the ASA) believe to be an "arbitrary" level of p=0.05—and *also* analyzed whether the directional trends in the data favor the treatment group or the placebo, even if such values did not reach traditional levels of statistical significance. (Dkt. 225-18, Kurzer Report ¶¶ 48-52; Dkt. 258-9, Kurzer Tr. 66:11—71:13.)

According to Dr. Kurzer, there are so many variables in human clinical research that "everything is stacked against [the] ability to see a true result." (Dkt. 258-9, Kurzer Tr. 67:9—68:14.) Thus, in Dr. Kurzer's opinion, "it is important to talk about trends because sometimes you may not be – you may not have enough statistical power to achieve significance. But if the trends of a number of endpoints are in the same direction, [] that is meaningful and that is worth reporting." (Dkt. 258-9, Kurzer Tr. 68:15-23.)

Dr. Kurzer's conclusion that there is competent and reliable scientific evidence to support the Challenged Claims is based on a number of different findings: (1) a finding of statistical significance on three different endpoints for participants who scored between a 0 and 1 on the AD8 scale; (2) a finding of statistical significance on three different endpoints for participants who scored between a 0 and 2 on the AD8 scale; and (3) directional trends in both the AD8 0-1 (five

[11] Dr. Schwartz also testified that "the very notion of firm[] statistical significance testing is coming under scrutiny by people who think about this, and I think it's not – it's no longer this sort of dogma that it once was." (Ex. A, Schwartz Tr. 167:8-12.)

endpoints, including the three that were statistically significant) and AD8 0-2 groups (six endpoints, including the three that were statistically significant) in the direction of a benefit as compared to placebo. (Dkt. 225-18, Kurzer Report ¶¶ 48-53; Dkt. 258-9, Kurzer Tr. 201:21—206:16.) In Dr. Kurzer's view, when, as here, a group of tests point "in the direction of benefit," you have "important result[s]" that are "unlikely to be explained by chance." (Dkt. 258-9, Kurzer Tr. 209:11—211:20.)[12]

Contrary to Plaintiffs' suggestion, Dr. Kurzer did not come up with this approach on her own, nor is it unique to her practice. Rather, she testified that her holistic approach to clinical trial data analysis is shared by many of her colleagues in the fields of nutrition, clinical trials, dietary supplements, and even statistics. (Dkt. 258-9, Kurzer Tr. 68:15-23, 201:21—207:16; *see also* Ex. E, Alexander Tr. 62:22—63:7 (when evaluating RCTs, "I certainly consider all elements of the published and reported data, if available, and epidemiology is about looking at patterns of associations, and it's investigating patterns of associations and trends."); Ex. A, Schwartz Tr. 162:24—163:8 (noting that the Madison Memory Study reported various "trends towards statistical significance"); Ex. A, Schwartz Tr. 166:9-20 (noting that while the importance of statistical significance was taught in graduate school, the thinking is "evolving" and now "one looks at the directional trends, one looks at the variability, and one tries to take the totality of data to determine if an effect is seen or not."); Ex. B, Wei Tr. 187:13—188:1.)

[12] Plaintiffs make much of the fact that Dr. Kurzer mistakenly switched the "direction" of benefit for two Cogstate tasks. The Cogstate battery allows for two different measurements for the two tests at issue (ONB and TWOB), each with a different directional benefit. (Ex. D at COGSTATE-000036.) But even accounting for this mistake, the Madison Memory Study data reflected six out of nine endpoints favoring apoaequorin in the AD8 0-2 group, with three such endpoints being statistically significant, and five out of nine endpoints favoring apoaequorin in the AD8 0-1 group, again with three endpoints being statistically significant. According to Dr. Kurzer, these results, along with the fact that no endpoint was statistically significant in favor of placebo in either subgroup, suggest that competent and reliable scientific evidence exists to support the Challenged Claims. (Dkt. 258-9, Kurzer Tr. 212:21—228:15.)

Plaintiffs' own authority does not support the argument that Dr. Kurzer's methodology is subjective and cannot be recreated. (Mot. at 26-27.) In *Tramontane v. HomeDepot USA, Inc.*, No. 15-cv-8528, 2018 WL 4572254, at *3 (S.D.N.Y. Sept. 24, 2018), a putative expert inspected a fractured ladder that had collapsed while in use, and concluded (1) that there was a manufacturing defect in a certain component of the ladder called a "J hook" which was caused by a number of flaws in the manufacturing process, and (2) that certain testing should have been performed on each and every J hook to ascertain porosity, which the expert opined was relevant to potential defect. The expert, however, did not describe the standard for manufacturing J hooks, did not explain what the final composition should have been, and, most importantly, did not even conduct his own recommended testing to analyze the porosity of the J hook at issue. *See id.* In other words, he failed to opine on all of the salient elements at issue related to the alleged failure and the methodology he employed. Thus, the court appropriately excluded the expert's testimony because there was "no scientific methodology" on which his theory could be tested, and that his report "beg[ed] the question" as to the appropriate level or porosity in a manufactured J hook and at what point porosity might constitute a defect. *Id.* at *7. Here, Dr. Kurzer explained her methodology in detail which, notably, considered the very same metrics that Plaintiffs' experts looked for—statistical significance of $p < 0.05$—as well as additional data points that Plaintiffs' experts did not consider.

Plaintiffs' reliance on *In re Mirena IUD Products Liability Litigation*, 169 F. Supp. 3d 396 (S.D.N.Y. 2016), offers no better help. There, the expert opined that the tips of an intrauterine device "contain[ed] relatively sharp edges compared to the smoother adjacent surfaces, based on [his] inspection under microscopy and with metrology." *Id.* at 440. To reach this conclusion, the expert "squeezed [the device] with a gloved hand and determin[ed], based on his own tactile

senses, that the tips are 'relatively sharp' compared to" adjacent, smoother surfaces. *Id.* Thus, the court rightly found that his methodology, which was based "primarily upon his own senses," could not be "recreated or reviewed because he provide[d] no standards by which he measured sharpness." *Id.* A similar result was reached in *In re GM LLC Ignition Switch Litigation*, No. 15-cv-1626, 2017 WL 6729295 (S.D.N.Y. Dec. 28, 2017). There, to confirm the plaintiff's theory regarding possible double ignition switch rotation followed by airbag deployment, the plaintiff's expert sat in his own parked car "and deliberately turned the ignition switch backward and forward with both his knee and his hand." *Id.* at *7. Again, the court properly excluded the expert's opinion because it was based "primarily upon his own senses," was "not scientific," and did "not amount to reliable expert testimony." *Id.*

In sharp contrast, here, *any* clinical trial expert, statistician, or even basic scientist for that matter, could recreate Dr. Kurzer's analysis by: (1) reviewing the data and statistical analysis of the Madison Memory Study, (2) ascertaining the endpoint for which statistical significance was found, and (3) determining whether the directional trend of the data favored apoaequorin or the placebo on each of the various endpoints.

Accordingly, Dr. Kurzer's data analysis was not subjective, could easily be recreated, and is accepted and utilized by the relevant scientific community, including those in the fields of clinical trials, statistics, nutrition, and epidemiology. As such, her method is reliable and her analysis of the Madison Memory Study data is admissible.

VI. PLAINTIFFS' ATTEMPT TO MISCHARACTERIZE AND EXCLUDE DR. GOODMAN'S TESTIMONY SHOULD BE REJECTED

From the outset of Plaintiffs' investigation of Prevagen more than seven years ago, Plaintiffs have maintained that Quincy has safety studies that purportedly "show that apoaequorin is rapidly digested in the stomach and broken down into amino acids and small peptides like any

other dietary protein." (Compl. ¶ 31.) According to Plaintiffs, and their expert Jeremey Berg, who admittedly is not an expert in human digestion, those studies allegedly demonstrate that Prevagen cannot work because (1) if apoaequorin has been "completely digested," it cannot cross the human blood brain barrier; and (2) if apoaequorin cannot cross the human blood brain barrier, it cannot have a beneficial effect on memory. (*Id*.) Defendants retained Dr. Goodman, who conducted the very studies that Plaintiffs rely upon, to correct Plaintiffs' misinterpretation of his prior work and to explain why Plaintiffs' and Dr. Berg's "complete digestion" theory is incorrect. Plaintiffs' attempt to limit Dr. Goodman's testimony therefore should be rejected.

Critically, Plaintiff *do not* seek to exclude Dr. Goodman's testimony in its entirety, but rather only seek to exclude: (1) his discussion of the digestion process wherein he provided numerous examples of proteins that show that Plaintiffs' "complete digestion" theory of the case is contrary to well-known principles of the human digestion process; and (2) his purported discussion about the potential absorption, bioactivity or mechanism of action for apoaequorin or byproducts that may result during the human digestion process. (Mot. at 28-34.) Plaintiffs merely attempt to exclude the portions of Dr. Goodman's opinion that do not support their argument.

Regarding the first point, Plaintiffs are asking this Court to let their own (unqualified) expert testify concerning the digestion properties of proteins and advance their own ill-conceived "complete digestion" theory, while excluding Dr. Goodman and Quincy from responding because it might hurt their chances of persuading the jury. This is improper. With respect to the second, Plaintiffs completely misunderstand (or intentionally distort) Dr. Goodman's opinions. Dr. Goodman is not testifying about the absorption, bioactivity, or mechanism of action *of apoaequorin*. He is, however, testifying that the theories concerning the byproducts of degraded

proteins advanced by Plaintiffs and Dr. Berg are incorrect and contrary to established scientific principles of human digestion. He provides numerous examples of proteins that show as much.

A. Dr. Goodman Should Be Permitted to Respond Fully to Plaintiffs' Flawed "Complete Digestion" Theory

Contrary to Plaintiffs' allegations, Quincy's safety studies do not show that apoaequorin is "completely digested" in the stomach and broken down into amino acids and small peptides. (Compl. ¶ 31.) Plaintiffs have not conducted any of their own testing on apoaequorin; rather, the sole basis for Plaintiffs' allegation is their incorrect interpretation of the data underlying Dr. Goodman's research. Indeed, while Plaintiffs make the guarded admission that Dr. Goodman "conducted some laboratory work on apoaequorin" (Mot. at 28 (emphasis added)), they ignore that this "laboratory work" is an *in vitro* allergenicity study and bioinformatics analysis conducted to determine the potential *allergenicity* of apoaequorin. As Dr. Goodman explains in his report, these studies were not designed to ascertain whether apoaequorin is "completely digested" in the human stomach. Nonetheless, it is the data from those studies conducted by Dr. Goodman that was included in the safety study that Plaintiffs plead "shows" apoaequorin is completely digested in the human stomach. (Dkt. 305-5, Goodman Aff. Report ¶¶ 19, 20; Compl. ¶ 31.) Accordingly, Dr. Goodman opined that his data does not "show that apoaequorin is rapidly digested in the stomach and broken down into amino acids and small peptides like any other dietary protein." (Dkt. 305-5, Goodman Aff. Report. ¶¶ 19-20.) Dr. Goodman further opined that there is no evidence to extrapolate as Plaintiffs do that pepsin digestion of proteins, *in general*, and of apoaequorin in particular would transform the proteins completely into single amino acids (i.e., "complete digestion"). (Dkt. 305-5, Goodman Aff. Report ¶ 36.)

Plaintiffs repeated their flawed theory through Dr. Berg's expert report, in which he, again without conducting any of his own testing on apoaequorin, and without sound basis, opined that

Dr. Goodman's "data demonstrate that apoaequorin is rapidly digested under conditions *intended to simulate the environment in the stomach*" and "provides strong evidence that apoaequorin does not survive in the stomach long enough to enter the bloodstream even if it were small enough to be absorbed. (Dkt. 258-12, Berg Report ¶ 25 (emphasis added).) Dr. Berg's opinion, like Plaintiffs' allegation, is based on a fundamentally flawed understanding of human digestion, namely that apoaequorin and other proteins *must* survive the human stomach wholly intact to have a therapeutic effect.

In response to Dr. Berg's report, Dr. Goodman submitted a rebuttal report, responding to Dr. Berg's "statements and opinions concerning the digestion of proteins in the human stomach and his incorrect interpretation and assumptions of the allergenicity work I performed for Quincy." (Dkt. 305-6, Goodman Rebuttal Report ¶ 2.) This report refutes Dr. Berg's statements that there is "evidence in the materials provided by Quincy Bioscience that apoaequorin is rapidly digested in the stomach as would be anticipated for almost all proteins." (Dkt. 258-12, Berg Report ¶ 11; *id.* ¶¶ 25-27 (discussing Dr. Goodman's allergenicity work for Quincy)). Dr. Goodman's testimony thus rebuts both points Plaintiffs seek to advance: (1) the "evidence" Dr. Berg relies upon (Dr. Goodman's work) does not show that apoaequorin is completely digested in the human stomach; and (2) the assumption that "almost all proteins" are completely digested in the human stomach is not accurate.

Plaintiffs' attempt to bar Dr. Goodman from correcting Plaintiffs' inaccurate interpretation of his work—despite the fact that he is the person most qualified to discuss what his work actually shows—should be rejected.

B. Dr. Goodman's Discussions of Other Proteins is Relevant to His Rebuttal of Plaintiffs' and Dr. Berg's Ill-Conceived "Complete Digestion" Theory

In further rebuttal, Dr. Goodman provides numerous examples of proteins that conclusively disprove Dr. Berg's assertion that an orally administered agent must completely survive the stomach to have a therapeutic effect. For example, Dr. Goodman discusses many published studies that show peptides, amino acids, or whole proteins are absorbed into the blood stream and incorporated into the breast milk of lactating mothers, which suggests that some proteins or amino acids are absorbed through the small intestine epithelium during the digestion process. (*See, e.g.* Dkt. 305-6, Goodman Rebuttal Report ¶15.) Dr. Goodman also discusses that ARA h 2 (a protein that is the major peanut allergen) has been identified in breast milk, the neural affect due to ingested proteins from some people who have Celiac disease, and the oral immunotherapy and subcutaneous immunotherapy of certain orally-administered proteins. (*Id.* ¶¶ 15-22.) These examples are necessary to rebut Plaintiffs' and Dr. Berg's categorically incorrect assertion that an orally-administered agent *must* completely survive the stomach to provide a therapeutic effect.

This testimony is unquestionably relevant and would not cause any prejudice to Plaintiffs. In fact, excluding Dr. Goodman's testimony would prejudice *Defendants*, as it would allow the jury to hear incorrect and overbroad testimony from Plaintiffs' (unqualified) expert that proteins generally cannot survive digestion and therefore cannot have a therapeutic effect (*see* Dkt. 258-12, Berg Rep. ¶ 17), yet shield them from hearing evidence about numerous examples of proteins or byproducts that disprove Berg's theory. Plaintiffs cannot have it both ways: they cannot simultaneously pursue their scientifically unsound "complete digestion" theory based on their erroneous interpretation of Dr. Goodman's work and then exclude Dr. Goodman from pointing out the fallacies of their incorrect theory.

Similarly misplaced is Plaintiffs' assertion that Dr. Goodman's discussion of the digestion characteristics of allergenic proteins must be excluded because apoaequorin is non-allergenic and therefore discussion of other proteins "has no bearing on this case." (Mot. at 31.) First, Plaintiffs cite no support for their bald assertion that potential differences in allergenic and non-allergenic proteins renders any portions of Dr. Goodman's testimony concerning protein digestion unreliable. And Plaintiffs acknowledge that Dr. Goodman's discussion is *not* limited to allergenic proteins. (Mot. at 32 (acknowledging proteins found in breast milk are not always allergens).) In any event, to the extent Plaintiffs do not agree with Dr. Goodman's "allergenic" protein examples, they are free to explore that disagreement through cross-examination. They certainly failed to proffer evidence from their own expert that supports their theory, who admittedly is not an expert in either allergy or digestion.

Moreover, none of the cases Plaintiffs rely upon support their position that Dr. Goodman's testimony will confuse or otherwise be unhelpful to the jury. *United States v. Ray*, 583 F. Supp. 3d 518 (S.D.N.Y. 2022), involved a criminal trial where the defendant was charged with numerous crimes related to his "target[ing] a group of college students and others for indoctrination and criminal exploitation, including extortion, forced labor, and prostitution." *Id.* at 524. The issue there was whether the defendant's expert's testimony was admissible under the Insanity Defense Reform Act of 1984 and Federal Rule of Criminal Procedure 12.2(b), which limits the admissibility of mental-health evidence in criminal cases in federal court as well as under the *Daubert* standard. *Id.* at 534-35. The court determined that there was "no method which another psychiatrist in the field could apply and arrive at the same conclusion regarding Ray's belief system" and there the defendant's expert admitted that his opinion "that Ray suffers from 'specific' and 'firmly-held' delusions does not reflect a clinical diagnosis" necessary to defeat the criminal

claims at issue. *Id.* at 540, 542. That simply has no bearing here, where Dr. Goodman discusses well-known protein digestion principles.

In *United States v. Aiyer*, 33 F.4th 97, 110 (2d Cir. 2022), an antitrust case, the district court excluded evidence of competitive effects as irrelevant in the context of that case "because price fixing and bid rigging are *per se* illegal" and it reasoned that the defendant should not be able to argue about the "pro-competitive effects of horizontal bid rigging or price fixing to make such practices legal." Plaintiffs' reliance on *In re Fosamax Products Liability Litigation*, 645 F. Supp. 2d 164, 198 (S.D.N.Y. 2009), is similarly misplaced. There, the court did not exclude testimony about general scientific principles as Plaintiffs ask this Court to do, but rather held that the "link" between the alleged similarities of "phossy jaw"— a condition observed in 19th and early 20th century factory workers—and the medical condition at issue was "not yet scientific enough for the courtroom." *Id.* at 198. Indeed, the proponent of the link had written that there is a "current lack of scientific support for the theory" that he was seeking to advance. *Id.* In *United States v. Grace*, 455 F. Supp. 2d 1181 (D. Mont. 2006), the court excluded the prosecution's use of a study to provide evidence of a causal relationship between Libby amphibole and incidence of asbestos-related disease because "those who conceived and executed the program disavowed any goal of establishing a causal relationship[between exposure to Libby amphibole and the incidence of asbestos-related disease" and the because the "study was designed for another purpose," its findings were irrelevant. *Id.* at 1190, 1195. And, in *United States v. Litvak*, 808 F.3d 160 (2d Cir. 2015), a securities fraud case, the expert's testimony was excluded as causing "potential confusion" because his testimony about whether the prices were "fair" did not have significant probative value in light of the fact that the price fairness was not an element of any of the crimes with which the defendant was charged. *Id.* at 185.

In short, Plaintiffs are seeking to exclude Dr. Goodman's testimony simply because it is at odds with their theory of the case, a theory that is based on a fundamental misunderstanding of the allergenicity study that he conducted. But that is not a valid basis to exclude Dr. Goodman's opinions, which are both relevant and proper rebuttal to Plaintiffs' and Dr. Berg's misguided theory of "complete digestion."

C. Dr. Goodman Does Not Testify About Mechanisms of Action or Bioactivity of Apoaequorin

Finally, Plaintiffs attempt to exclude Dr. Goodman's purported testimony "about the absorption or bioactivity of apoaequorin" and "potential mechanisms of action." (Mot. at 33-34.) This is yet another strawman argument, as Dr. Goodman offered no such opinions. Again, Dr. Goodman is simply *refuting Plaintiffs'* unsupported assumption that *all* dietary proteins are completely digested by providing examples of orally-administered proteins, degraded into peptides with bioactive properties that result in a therapeutic effect. (Dkt. 305-5, Goodman Aff. Report ¶¶ 19-20.) As a world-renown expert on allergenicity of food products, the manager of the AllergenOnline.org database, the Chairman of the WHO/IUIS Allergen Nomenclature Subcommittee, a Fellow in the American Academy of Allergy, Asthma and Immunology, and a member of the European Academy of Allergy and Clinical Immunology, the American College of Allergy, Asthma and Immunology, the American Association of Immunologists, the American Chemical Society, and the Institute of Food Technologists with dozens of peer reviewed scientific journal articles on the topic (Dkt. 305-5, Goodman Aff. Rep., ¶¶ 7-8, Ex. A), Dr. Goodman is not only *qualified* to offer such opinions, but is perhaps the *most* qualified expert in this case to address Plaintiffs' misunderstanding (or misinterpretation) of his own research. He is certainly more qualified in this area than Dr. Berg, who (despite being retained in part to rebut Dr. Goodman's

opinions) admittedly is *not* an expert in human digestion. (Dkt. 307 at 20-22.) Plaintiffs' Motion should be denied.

VII. DR. GORTLER'S REBUTTAL REPORT SHOULD BE ADMITTED AS PROPER REBUTTAL TO THE EXPERT REPORT OF DR. BERG

Plaintiffs' challenges to the rebuttal report of pharmacologist and professor Dr. Gortler—offered to rebut the conclusions rendered by Dr. Berg—are unavailing. These challenges rest on a faulty premise about the role of Dr. Gortler's testimony. The purpose of Dr. Gortler's rebuttal was to highlight the significant holes in Dr. Berg's broad-based conclusion that he had "not seen evidence in the literature or otherwise that apoaequorin could have *any* therapeutic effect on the body through *any other* mechanism of action"—***not*** to render definitive conclusions of his own about how apoaequorin (or Prevagen) works. Dr. Gortler directly challenged Dr. Berg's outdated and unformed theories, drawing on Dr. Gortler's own background and expertise; as part of Dr. Berg's analysis, he offered other concededly *possible* mechanisms of action and concededly *possible* therapeutic effects for apoeaquorin. But, of course, Dr. Gortler never sought to *prove* these possible mechanisms of action or effects; rather, he raised their theoretical application to undermine Dr. Berg's lack of qualifications and to demonstrate the severe limitations of Dr. Berg's opinion related to mechanism of action. Given Plaintiffs' reliance on Dr. Berg's broad-based conclusion, Dr. Gortler's rebuttal report is directly relevant to Quincy's defenses and essential for the jury's assessment of Plaintiffs' purported expert evidence.

A. Dr. Gortler Rebuts Dr. Berg's Conclusion that Prevagen and Apoaequorin Need a Known Mechanism of Action to Prove Therapeutic Effect

In his rebuttal report, Dr. Gortler opined that: (1) mechanisms of action need not be known in order for a drug to provide a therapeutic effect (Dkt. 305-8, Gortler Rebuttal Report ¶ 37); and (2) that the FDA does not require a known mechanism of action in order to receive approval. (*Id.* ¶ 38.) Plaintiffs' argument that these opinions do not specifically rebut Dr. Berg's report defies

logic. Dr. Berg's entire report rests on the premise that because Dr. Berg could not pinpoint a mechanism of action for apoaequorin, that necessarily means that Prevagen cannot have a clinical effect. (Dkt. 258-12, Berg Report ¶¶ 13-14 ("Due to the clear evidence that apoaequorin cannot enter either the bloodstream or the brain, I briefly consider some alternative possible mechanisms by which Prevagen might have a therapeutic effect. Each of these mechanism theories is substantially flawed. Ultimately, it is clear that Prevagen and its active ingredient apoaequorin have not been shown to have any therapeutic effect on humans."); *see also id.* ¶¶ 51, 55.) In other words, Dr. Berg reaches his conclusion about Prevagen's clinical efficacy *only* by purportedly examining (and dismissing) certain potential "mechanisms of action" for Prevagen and apoaequorin. Dr. Gortler's opinions that a dietary supplement (or drug, for that matter) *does not require* a known mechanism of action to have a therapeutic effect on humans—and that the FDA *does not even require* a mechanism of action—therefore plainly rebut Dr. Berg's unqualified conclusion.[13] Accordingly, those statements are squarely relevant to Dr. Gortler's rebuttal of Dr. Berg's report and should not be excluded.[14]

B. Dr. Gortler Rebuts Dr. Berg's Conclusion that Prevagen and Apoaequorin Lack a *Possible* Mechanism of Action by Presenting Other *Possible* Mechanisms of Action that Dr. Berg Failed to Consider

Plaintiffs' issues with Dr. Gortler's discussion of the effectiveness of other drugs and substances similarly reflect a lack of understanding of the purpose of his report. At the outset of

[13] Plaintiffs' characterization of Dr. Gortler's position that a drug does not require a mechanism of action in order to work as "unremarkable" is interesting because Dr. Berg implied the exact opposite in his report. Plaintiffs' own admission that there is no requirement for a mechanism of action to demonstrate efficacy rebuts Dr. Berg's report and provides a further reason why his report should be excluded in its entirety. (*See* Dkt. 307 at 19-26.)

[14] The case Plaintiffs cite in support of this argument actually supports Defendants' position. In *ProBatter Sports LLC v. Sports Tutor, Inc.*, the court *accepted* the majority of the challenged rebuttal report because it critiqued another expert report by pointing out unjustified or "incorrect assumption[s]" in the other expert's analysis. No. 3:05-CV-1975, 2020 WL 10433595, at *2-3 (D. Conn. Aug. 21, 2020). Indeed, the only portions of the report that were excluded were portions that "d[id] not constitute rebuttal evidence." *Id.* at 3. As Dr. Gortler's statements are made solely to challenge statements made by Dr. Berg, they constitute rebuttal evidence and should be admitted.

his rebuttal report, Dr. Gortler made clear that part of his mandate was "to respond to Dr. Berg's statements ***from the perspective of a pharmacologist***." (Dkt. 305-8, Gortler Rebuttal Report ¶ 2 (emphasis added).) That task entailed responding to Dr. Berg's ultimate conclusion that—because it lacked a known mechanism of action— "it is clear that Prevagen and its active ingredient apoaequorin have not been shown to have *any therapeutic effect* in humans." (Dkt. 258-12, Berg Report ¶ 14.)

To respond to Dr. Berg's broad-based, unsupported conclusion, Dr. Gortler—a celebrated pharmacologist, who has spent significant time at with the FDA spanning multiple presidential administrations—demonstrates how other drugs with and without mechanisms of action are effective in human beings to highlight the *possibility* that Prevagen and apoaequorin *could* be similarly effective. (Dkt. 305-8, Gortler Rebuttal Report ¶ 41 (stating that Dr. Berg's report "neglects to consider the obvious possibility that one or more of the individual metabolized components of Prevagen could eventually be transported or absorbed and interact with receptors in the form of a *prodrug*); *id.* ¶ 62 (after examination of large microorganisms that can survive in the stomach, stating "Dr. Berg's blanket assertion that Prevagen's active ingredient cannot survive digestion due to its size, and could never have pharmacological activity in the body merely because of its size, without providing objective scientific data to support this conclusion, is contrary to well-founded pharmacological and other scientific concepts.").) Contrary to Plaintiffs' positions, Dr. Gortler does not need to make any further connections between those other drugs and Prevagen to make the point that *Dr. Berg failed to consider other potential mechanisms of action* and thereby rebut Dr. Berg's unqualified, broad conclusion.[15] *See In re Specialist & Other Vessel Owner*

[15] Plaintiffs' ignorance of the posture of Dr. Gortler's report is underscored by the cases cited in support of their contentions, none of which assesses *rebuttal* expert testimony. *See Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 21 (2d Cir. 1996) (assessing admissibility of affirmative expert testimony regarding lost earnings); *In re Fosamax*, 645 F. Supp. 2d at 198 (assessing admissibility of affirmative expert testimony on causation in products liability

Limitation Actions, No. 16 Civ. 4643, 2020 WL 8665287, at *2 (S.D.N.Y. June 30, 2020) ("Federal Rule of Procedure 26 permits parties to submit expert testimony that is intended solely to contradict or rebut evidence on the same subject matter identified by another party" and "[r]ebuttal evidence is properly admissible when it will explain, repel, counteract, or disprove the evidence of the adverse party"); *Scott v. Chipotle Mexican Grill, Inc.*, 315 F.R.D. 33, 44 (S.D.N.Y. 2016) ("When offering expert testimony, the defendant has 'no burden to produce models or methods of their own; they need only attack those of the plaintiffs' experts.'" (quoting *In re Zyprexa Prods. Liabl. Litig.*, 489 F. Supp. 2d 230, 285 (E.D.N.Y. 2007))).

For example, Dr. Gortler's discussion of Alzheimer's disease and calcium-binding is relevant because it links a known cause of memory loss (excess calcium) with a known property of apoaequorin (its ability to bind and reduce calcium) to present a *possible* mechanism of action for apoaequorin to rebut Dr. Berg's conclusion that none exist. Plaintiffs' response to this plainly relevant testimony is that, based on statements to the FDA, Quincy has "abandoned" the position that apoaequorin may reduce calcium in the brain. But simply because some of Quincy's experts described this theory as "original" or prevalent "earlier" in time does not amount to Quincy's wholesale abandonment of this possible mechanism of action, nor does it mean that Quincy no longer believes this mechanism to be a possibility. Indeed, these possible mechanisms of action are not mutually exclusive; at this point in time, they are plausible theories that, in any event, have no bearing on apoaequorin's efficacy. Plaintiffs also suggest that Defendants' other experts contradict Dr. Gortler's testimony on the possibility that apoaequorin could pass through the blood-brain barrier and help reduce calcium in the brain (again, presented solely as a *possible*

dispute); *Borsack v. Ford Motor Co.*, No. 04 Civ. 3255, 2009 WL 5604383, at *1-3 (S.D.N.Y. Feb. 3, 2009) (assessing admissibility of affirmative expert testimony on causation in personal injury dispute).

mechanism)—but this argument both misstates the purpose of Dr. Gortler's hypothetical and also overstates the conclusions of Defendants' other experts, who have never definitively concluded otherwise regarding the blood-brain barrier. (*See* Dkt. 225-18, Kurzer Report ¶ 56 (stating that "it is *unlikely*" that apoaequorin enters the brain); Ex. A, Schwartz Tr. at 260:7-18 (stating that it would "make[] sense" that apoaequorin was metabolized in the digestive tract).)

Plaintiffs' misunderstanding of the *purpose* of the rebuttal report permeates the rest of their arguments. Plaintiffs harp on whether Dr. Gortler explained why orally consumed apoaequorin could have the same effect on human brain cells as apoaequorin injected into a rat's brain—but, again, as a rebuttal expert, Dr. Gortler's role is to undermine Dr. Berg's extreme position that there is no *possible* way for Prevagen or apoaequorin to have a therapeutic effect on humans. *See In re Specialist*, 2020 WL 8665287, at *2; *Scott*, 315 F.R.D. at 44.

Dr. Gortler's testimony that consuming apoaequorin together with dietary cholesterol "has the potential to 'greatly facilitate' the uptake of intact protein from the gut" is similarly reliable, relevant *rebuttal* testimony. Plaintiffs attack Dr. Gortler's knowledge and expertise in this area, ignoring Dr. Gortler's decades of experience as a pharmacologist and pharmacist and, most importantly, that he is testifying simply to the *conclusions rendered* in the studies he cites. (Dkt. 305-8, Gortler Rebuttal Report ¶¶ 4-30 (detailing Dr. Gortler's education and experience); *id.* ¶¶ 64-65 (discussing published studies and data supporting statement that dietary intake of apoaequorin together with dietary cholesterol has the potential to "greatly facilitate" the uptake of intact protein from the gut).) Contrary to Plaintiffs' limited read of Dr. Gortler's role, courts have consistently held that experts who have "expertise in the field covered" by studies conducted by others are permitted to interpret their results as part of their reports. *See, e.g.*, *Hart v. BHH, LLC*,

2018 WL 3471813, at *8 (allowing expert to opine on outside studies and experiments where expert was "more than qualified to interpret their results"); *Medisim Ltd.*, 861 F. Supp. 2d at 169.

The cases Plaintiffs cite are factually distinct as they are not about an expert in a field opining on published studies in that field. *See AU New Haven, LLC v. YKK Corp.*, No. 15 Civ. 3411, 2019 WL 1254763, at *12 (S.D.N.Y. Mar. 19, 2019) (excluding certain portions of expert testimony in patent litigation that referenced statements made in *marketing materials* because expert "did not rely" on those statements to reach his ultimate conclusions); *Rotman v. Progressive Ins. Co.*, 955 F. Supp. 2d 272, 283 (D. Vt. 2013) (excluding portions of causation expert's testimony in personal injury case where expert was "recast[ing] the testimony of" *a lay witness* "to arrive at a theory of causation").

Here, there is no question that Dr. Gortler is qualified to interpret and opine on studies conducted by other experts in his field, and Plaintiffs offer no argument or case suggesting otherwise.

C. Dr. Gortler's Testimony Regarding the Madison Memory Study and Prevagen's Safety Rebuts Dr. Berg's Testimony that Prevagen and Apoaequorin Have No Therapeutic Effect.

Similarly, Dr. Gortler's testimony regarding the Madison Memory Study and Prevagen's safety constitutes proper rebuttal testimony and should be admitted. Dr. Berg's report specifically addresses Prevagen's safety by criticizing Quincy's statements to the FDA claiming that Prevagen should be "[g]enerally recognized as safe." (Dkt. 258-12, Berg Report ¶ 29.) Dr. Gortler is therefore within his rights as a rebuttal expert to respond to that criticism.

Nor would any reference to Prevagen's safety (whether it be offered by Drs. Gortler, Katz, Schwartz or Kurzer) distract the jury or waste its time. Plaintiffs apparently think too little of a jury if they believe that testimony about safety would impact their views on the advertising claims for Prevagen. Finally, Dr. Gortler's limited references to the results of the Madison Memory Study

(Dkt. 305-8, Gortler Rebuttal Report ¶¶ 86-88) again serve to rebut Dr. Berg's broad conclusion that Prevagen and apoaequorin have "no therapeutic effect." This limited reference to the Madison Memory Study does not constitute Dr. Gortler's expert opinion ***on*** the Madison Memory Study; rather, it responds to Dr. Berg's baseless claim that there is no evidence of Prevagen's clinical efficacy. This is helpful and appropriate rebuttal testimony.

VIII. DRS. KURZER, SCHWARTZ, AND KATZ'S TESTIMONY REGARDING APOAEQUORIN'S POTENTIAL MECHANISMS OF ACTION REBUTS *PLAINTIFFS'* THEORIES ON MECHANISMS OF ACTION AND SHOULD BE ADMITTED.

Plaintiffs also challenge the portions of Dr. Kurzer, Dr. Schwartz, and Dr. Katz's expert testimonies that identify potential mechanisms of action for apoaequorin. (Opp. at 42-46.) Again, Plaintiffs' argument ignores that this testimony—much of which appears in *rebuttal* reports—is offered in response to *Plaintiffs'* position that there is no evidence that apoaequorin has a fully known mechanism of action therefore it has no therapeutic effect. Like Dr. Gortler, Drs. Kurzer, Schwartz, and Katz do nothing more than present *plausible* mechanisms of action for Prevagen to undermine the underpinning of the impermissible logical leap that Plaintiffs ask this Court to make. Ultimately, Plaintiffs' challenges of Quincy's expert testimony centered on mechanisms of action amount to nothing more than an attempt to have their cake and eat it too by seeking to have their broad, unsupported, outdated theories go unchallenged before a jury. *Plaintiffs* proffered the claim that there is no evidence that Prevagen has a therapeutic effect because there is no evidence of its mechanism of action (*see* Compl. ¶ 31), and now *Plaintiffs* seek to eliminate all expert testimony proffered by Quincy that calls that broad, unqualified, and unsupported conclusion into question. This Court should not condone Plaintiffs' efforts and should accordingly permit Defendants' experts to rebut their unsupported conclusions.

A. Dr. Kurzer's Limited Testimony Regarding Apoaequorin's Potential Mechanisms of Action Rebuts Plaintiffs' Positions and Should be Admitted

Dr. Kurzer's limited testimony regarding the mechanism of action for Prevagen is directed to a specific paragraph in the Complaint in which Plaintiffs baselessly opine that "apoaequorin is rapidly digested in the stomach and broken down into amino acids and small peptides like any other dietary protein," and accordingly "cannot cross the human blood brain barrier or enter the human brain." (Dkt. 225-18, Kurzer Report ¶ 54 (quoting Compl. ¶ 31).) Plaintiffs continue in the Complaint to state that "the absorption of AQ/Prevagen *is not yet fully understood* and therefore the exact mechanism by which AQ influences cognitive function *is not known at this time.*" (Compl. ¶ 56 (emphasis added). In response to this allegation, Dr. Kurzer presents plausible mechanisms explaining how that apoaequorin could influence brain function without entering the brain by referencing other compounds that do so. (Dkt. 225-18, Kurzer Report ¶¶ 56-57.) Dr. Kurzer does not—nor is she required to—definitively conclude that apoaequorin influences brain function through these plausible mechanisms of action to rebut Plaintiffs' conclusions—her testimony is offered to simply attack the broadness and inflexibility of Plaintiffs' allegations in the Complaint.[16] *See Scott*, 315 F.R.D. at 44.

B. Dr. Schwartz's Testimony Regarding Apoaequorin's Mechanism of Action Rebuts Plaintiffs' Positions and Should be Admitted

Dr. Schwartz's discussion of Prevagen's mechanism of action is limited to rebutting Plaintiffs' allegations that Prevagen cannot work because its mechanism of action is unknown. Specifically, Dr. Schwartz agrees with Plaintiffs that Prevagen's mechanism of action is "not completely understood" (Dkt. 225-23, Schwartz Report ¶¶ 13, 62-63, 71, 74-75), but then further

[16] Again, the case Plaintiffs cite in support of this point focuses on affirmative expert testimony, not *rebuttal* testimony, and is inapplicable here. *See Mancuso v. Consolidated Edison Co.*, 967 F. Supp. 1437, 1441 (S.D.N.Y. 1997) (assessing admissibility of expert testimony in medical malpractice case).

opines that understanding a dietary supplement's mechanism of action is *not necessary* for that substance to have "scientifically well-established clinical benefits." *Id.* To substantiate these statements, Dr. Schwartz points to examples of other substances that lack known mechanisms of action (*e.g.*, seaweed extract, Forasyn Connect) but have "well documented benefits on cognitive functioning" (*Id.* ¶ 63), and evidence of other drugs that function through other, *plausible* mechanisms of action that he identifies. (*Id.* ¶¶ 71-75.) Indeed, Dr. Schwartz testified at his deposition that he "wouldn't have even really brought up mechanism of action if it weren't for my *general* notion in my initial report that there were criticisms of Prevagen because of its mechanism of action" or theories regarding Prevagen's mechanisms of action proffered by Dr. Berg precisely because "mechanism of action is not a critical feature of substantiating the benefits of a dietary supplement." (Ex. A, Schwartz Tr. 265:18—266:1.)

Plaintiffs' claims that Dr. Schwartz's testimony is improperly speculative miss the point. At its core, Dr. Schwartz's testimony is that while Prevagen's mechanism of action is unknown, that fact has no bearing on whether it has a therapeutic effect. (Dkt. 225-23, Schwartz Report ¶¶ 13, 62-63, 71, 74-75.) There is nothing speculative about that statement—it is an opinion buttressed by Dr. Schwartz's clinical experience and professional judgment, as well as the substantiating facts in the report about other clinically effective nutritional supplements and foods with no known mechanism of action, including Fortasyn Connect (a combination of nutrients with well documented benefits on cognitive functioning) and oligomannate (a seaweed extract used to improve cognitive function in individuals with Alzheimer's disease). (*Id.* ¶ 63.) These references to other substances—either by identifying effective supplements that lack a known mechanism of action or by identifying other plausible mechanisms of action that *could* be at play—are included only to prove that main point, not to speculate on how Prevagen or apoaequorin work. The

relevance and value of Dr. Schwartz's testimony therefore does not therefore turn on the similarity of these other drugs to Prevagen or apoaequorin to make them relevant to rebutting *Plaintiffs*' theories regarding Prevagen's mechanism of action and his testimony on these points will help, not hurt, the jury render its verdict.

C. Dr. Katz's Testimony Regarding Apoaequorin's Mechanism of Action Rebuts Plaintiffs' Positions and Should be Admitted

For all the same reasons, Dr. Katz's testimony regarding Prevagen and apoaequorin's mechanism of action constitutes proper rebuttal testimony to Plaintiffs' conclusions regarding Prevagen and apoaequorin's mechanism of action. Specifically, Dr. Katz identifies a number of anticipated objections from Plaintiffs, one of which is that "[b]ecause apoaequorin does not cross the blood brain barrier in humans, there is no plausible mechanism of action." (Dkt. 225-15, Katz Report ¶ 50.) Dr. Katz then *responds* to this anticipated objection by discussing the plausibility of apoaequorin crossing the blood brain barrier, other potential mechanisms of action for apoaequorin, and the fact that numerous other substances have an unknown or poorly understood mechanism of action." (*Id.* ¶¶ 67-70.) Dr. Katz does not, as Plaintiffs claim, make concrete conclusions about whether these *plausible* mechanisms of action are at play; he merely seeks to respond to Plaintiffs' broad conclusion that there is no *plausible* mechanism of action for apoaequorin by pointing to other possibilities. This testimony should be allowed.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court deny Plaintiffs' Motion in its entirety, along with such other and further relief as the Court deems appropriate.

Date: October 3, 2022

KELLEY DRYE & WARREN LLP

By: /s/ *Geoffrey W. Castello*

John E. Villafranco (*pro hac vice*)
Geoffrey W. Castello
Damon W. Suden
Jaclyn M. Metzinger
Glenn T. Graham
3 World Trade Center
175 Greenwich Street
New York, NY 10007
Tel: (212) 808-7800
Fax: (212) 808-7897
jvillafranco@kelleydrye.com
gcastello@kelleydrye.com
dsuden@kelleydrye.com
jmetzinger@kelleydrye.com
ggraham@kelleydrye.com

Counsel for Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc. and Quincy Bioscience Manufacturing, LLC

COZEN O'CONNOR, P.C.

By: */s/ Michael de Leeuw*

Michael de Leeuw
Tamar S. Wise
3 World Trade Center
175 Greenwich Street
New York, NY 10007
Tel: (212) 908-1331
mdeleeuw@cozen.com
twise@cozen.com

Counsel for Defendant Mark Underwood

CERTIFICATE OF SERVICE

I certify that on this 3rd day of October, 2022, I caused to be served (1) Defendant's Memorandum of Law in Opposition to Plaintiffs' Motion to Exclude the Testimony of Drs. David Schwartz, David Katz, Lee-Jen Wei, Mindy Kurzer, Richard Goodman, and David Gortler; and (2) the Declaration of Glenn T. Graham and exhibits affixed thereto, to be made by electronic filing with the Clerk of the Court using the CM/ECF system, which will send a Notice of Electronic Filing to all counsel of record.

Date: October 3, 2022 KELLEY DRYE & WARREN LLP

By: /s/ *Geoffrey W. Castello*
Geoffrey W. Castello